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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,086	07/30/2001	Alan Ebringer	09262-027-51	2308

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,086	EBRINGER, ALAN	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004 and 14 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed September 17, 2004 and May 14, 2004 in response to the Office Action of June 30, 2003 is acknowledged and has been entered. Claims 1-10 have been cancelled. Claims 11-36 have been added and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Examiner and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Examiner Ulrike Winkler Group Art Unit 1648.**

Claim Rejections - 35 USC § 101

The rejection of claims 8 and 10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter **is withdrawn** in view of applicants cancellation of the claims.

Claim Rejections - 35 USC § 112

The rejection of claims 5 and 8-10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of applicants cancellation of the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3, 4, 7 under 35 U.S.C. 102(b) as being anticipated by Ebringer et al. (Environmental Health Perspectives, 1997) or Erbringer (WO98/13694) **is withdrawn** in view of applicants cancellation of the claims.

New rejections in view of applicants newly presented claims:

Claim Rejections - 35 USC § 102/§ 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 11, 19, 20 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Terryberry et al. (Neurobiology of Aging, 1998).

The instant invention is drawn to a method of diagnosing a demyelinating disease or a spongiform disease. The detection is not limited to the specific disease listed, BSE, MS or CJD.

The assay requires the detection of antibodies to myelin, neurofilaments or Acinetobacter. The claims are also drawn to a kit.

Terryberry et al. disclose the testing of autoantibodies to neurofilament and myelin basic protein in the sera of patients having Parkinson's disease, amyotrophic lateral sclerosis or relapsing-remitting multiple sclerosis (see table 1, and material and methods see EIA protocol). The assay detects antibodies to myelin basic protein and neurofilaments, in patients with demylenetaing disease. The findings of this study indicate that antibodies to neurofilament and myelin are commonly found in neurodegenerative disease (see page 213, column 1, last paragraph). Therefore, the instant invention is anticipated.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to package the antigens for diagnostic purposes. One having ordinary skill in the art would have been motivated to package the required components into a kit for the sake of conveniently providing the reagents to unskilled personnel. Therefore, the instant invention would have been obvious to those of ordinary skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebringer A. (WO 98/13694), Terryberry et al. (Neurobiology of Aging, 1998), Sotelo et al. (Science 1980) and Toh et al. (Proceeding of the National Academy of Science, 1985).

Ebringer (WO 98/13694) teaches the detection of antibodies to *Acinetobacter calcoaceticus* using peptide antigens having the sequence of ISRFAWGEV (see claims). The reference teaches assaying for IgA, IgG and IgM antibodies (see page 4, 3rd paragraph). The reference correlates the presence of antibodies to *Acinetobacter calcoaceticus* in bovine with BSE disease.

Terryberry et al. (Neurobiology of Aging, 1998) teaches the testing of autoantibodies to neurofilament and myelin basic protein in the sera of patients having Parkinson's disease, amyotrophic lateral sclerosis or relapsing-remitting multiple sclerosis (see table 1, and material and methods see EIA protocol). The assay detects antibodies to myelin basic protein and neurofilaments, in patients with demyelinating disease. The findings of this study indicate that antibodies to neurofilament and myelin are commonly found in neurodegenerative disease (see page 213, column 1, last paragraph).

Sotelo et al. (Science 1980) teaches the detection of autoantibodies to neurofilaments in patients with kuru and CJD.

Toh et al. (Proceeding of the National Academy of Science, 1985) teaches the detection of antibodies, IgG, to neurofilaments in patients with kuru and CJD.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to detect antibodies to myelin, neurofilaments and *Acinetobacter calcoaceticus* using peptide antigens. The prior art discloses that an increase to these autoantibodies correlates with

demyelinating disease. The prior art also indicates that IgA, IgG and IgM antibodies can be detected using the antigens. In the absence of unexpected results, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of the references to detect antibodies in a patient suspected of suffering from a demyelinating disease. The instant situation is amenable to the type of analysis set forth in *In re Kerkhoven*,205 USPQ 1069 (CCPA 1980) wherein the court held that it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, given the teaching of the prior art of processes using antigens to detect antibodies in a patient sample and correlate it with a disease state because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as for detection for the same purpose. One of ordinary skill in the art would have reasonably expectation of success when using the antigens in a combined assay.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to package the antigens for diagnostic purposes. One having ordinary skill in the art would have been motivated to package the required components into a kit for the sake of conveniently providing the reagents to unskilled personnel. Therefore, the instant invention would have been obvious to those of ordinary skill in the art.

Therefore, the instant invention is obvious over the cited references.

Claim Objections

Claims 12, 18, 25, 29, 33, 34 are objected to because of the following informalities: The claims make reference to a peptide sequence without using a sequence identifier. Appropriate correction is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 11/14/05